

AMENDMENTS TO THE SPECIFICATION:

Please replace the paragraph on page 4, beginning on line 22, with the following new paragraph:

A preferred coating for the metal valve components is a very thin layer of glass, or other material, deposited by gas vapor deposition. Such coating is preferably used on all of the metal valve components in contact with the formulation, including the inside and outside of the metering chamber, inside and outside of the bottle emptier (if any), and the inside and outside of the valve stem (if metal), and may also be used to coat the inside of the canister. The preferred such coating technique is the ~~Silcosteel~~ SILCOSTEELTM process available from Restek Corporation, Bellefonte, Pa. The ~~Silcosteel~~ SILCOSTEELTM aspect of the invention is useful even outside the context of the chemical degradation problem, for both solution and suspension formulations.

Please replace the paragraph on page 6, at line 15, with the following new paragraph:

Fig. 2 is the same as ~~is~~ Fig. 1, but with modified valve configuration~~[[.]]; and~~

Please add the following new paragraph on page 6, at line 16:

FIGS. 3-5 (Graphs A-C) show comparative impurity levels.

Please replace the paragraph on page 10, beginning on line 4, with the following new paragraph:

A preferred coating for the metal valve components is a very thin layer of fused silica glass, or other material, deposited by gas vapor deposition. Such coating is preferably used on all of the metal valve components in contact with the formulation, including the inside and outside of the metering chamber, inside and outside of the bottle emptier (if any), and the inside and outside of the valve stem (if metal). The preferred such coating technique is the ~~Silcosteel~~ SILCOSTEELTM process available from Restek Corporation, Bellefonte, Pa. This process deposits a submicron layer of fused silica glass on the metal components and can be used both on the valve components and on the interior of the canister. Not only is it helpful in preventing chemical reaction with the metal, but passivation of the metal surface using the ~~Silcosteel~~ SILCOSTEELTM process can provide a smooth surface on, for example, the valve stem so as to reduce friction and help prevent valve clogging, and can also reduce oxidation of the metal that can introduce particulate material into the system. The ~~Silcosteel~~ SILCOSTEELTM aspect of the invention is thus useful even outside the context of the chemical degradation problem, for both solution and suspension formulations. The ~~Silcosteel~~ SILCOSTEELTM process is performed at a temperature of 400°C, which has the added benefit of thermally removing residual oils on the metal surface.

Please replace the paragraph on page 16, beginning on line 19, with the following new paragraph:

~~The following~~ Fig. 3 (Graph A) shows comparative ~~tests~~ test results on a budesonide solution formulation comprising 0.22% w/w budesonide, 11% w/w ethanol, and the remainder 134a. Three lots were stored at 40°C/75% RH. One lot (identified

as "Coated A") was contained in aluminum cans coated with an epoxy-phenolic coating (Cebal Printal Ltd. U.K.) and capped with a blind ferrule and a continuous gasket (made of DFDB 1085 elastomer, Union Carbide) so as to completely isolate the formulation from contact with metal surfaces. Another lot ("Coated B") was contained in the same type of cans as Coated A, but equipped with a functional valve ferrule (3M Neotechne ~~Spraymiser~~ NEOTECHNIC SPRAYMISERTM solution valve) having a solution gasket to partially prevent contact of the formulation with the underside of the valve ferrule. A third lot ("Uncoated") was contained in uncoated aluminum cans equipped with the same valves as for Coated B.

On page 17, please delete Graph A.

Please replace the paragraph on page 17, beginning on line 5, with the following new paragraph.

The same type of comparison (using the same kind of Coated A, Coated B, and Uncoated containers as in Example 7) was made for formulation Examples 8 and 9. In Example 8 the formulation contained 0.22% w/w budesonide dissolved in a mixture of 134a and 13% w/w ethanol. The Example 9 formulation had 0.17% w/w budesonide dissolved in 134a and 15% w/w ethanol. In both cases, shown in Figs. 4 and 5 (Graphs B and C), respectively, the degradation rate was much greater in the Uncoated can, and degradation was least for Coated A.

On page 18, please delete Graph B.

On page 19, please delete Graph C.

Please replace the paragraph on page 19, beginning on page 5, with the following new paragraph:

Test was also conducted on solution formulations of about 0.2% w/w budesonide, 13% anhydrous ethanol, and 134a to determine the effect of different coating types on chemical stability. Two types of canister coatings were compared: phenolic epoxy coating (Cebal) vs. an FEP coating (teflon-like polymer) from DuPont. Coated and uncoated valves similar to the design of FIG. 2 were compared: uncoated valves ("UV") vs. coated valves ("CV") with Restek's ~~SilcoSteel~~ SILCOSTEEL™ coated parts. The interior and exterior surfaces of the valve stem, metering tank, and bottle emptier were made of stainless steel and were coated with a submicron layer of fused silica. The results are summarized in Tables 6 and 7 below.